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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,737	10/29/2001	Shuki Vitek	266/083	9679
23639	7590	03/09/2006		
BINGHAM, MCCUTCHEN LLP THREE EMBARCADERO CENTER 18 FLOOR SAN FRANCISCO, CA 94111-4067			EXAMINER JUNG, WILLIAM C	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/020,737	Applicant(s) VITEK ET AL.	
	Examiner William Jung	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed December 16, 2005 have been fully considered but they are not persuasive.

After further consideration of the applicant's remarks, examiner respectfully disagrees.

In regard to claims 1 and 17, the applicant's argues that Seale does not teach method and system where the disturbance of focused ultrasound beam path is detected during a certain period of time to determine one or more characteristics of the disturbance. Examiner would like to clarify that the claimed language in claims 1 and 17 only reflects detecting disturbance of ultrasound beam path, which Seale clearly anticipates in col. 5, lines 24-28. Since, ultrasound transmission and reception are inherently set at certain focal depth, the time period to obtain the perturbation in beam path is dependent on the focal depth. The characterization of the disturbance in claims 1 and 17 is not clearly defined as what function the analysis serves. Therefore, Seale's application of using perturbation detection to control the alignment of the ultrasound transducer is no different than the claimed invention in claims 1 and 17. Thus, examiner maintains the previous rejection from office action dated August 25, 2005 and repeated below.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. Claims 1 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by *Seale* (US 5,844,140).

Seale anticipates all claimed features in claims 1 and 17.

Claims 1 and 17: Seale discloses a method and apparatus for sensing or detecting a disturbance or perturbation in a transmission path of a converging ultrasound energy beam transmitted by a transducer in a focused ultrasound system where the transmission of ultrasound energy is from the transducer along a transmission path to a focal area or zone, detecting whether a reflected portion of the ultrasound energy is received by the transducer has flight of time or time period after transmission where the time period indicates the location of perturbation to locate the path and depth of the focal zone and the determining the characteristics of the disturbance such as direction and path, and depth (col. 5, lines 14-28; col. 14, line 12 – col. 16, line 55).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-16, 18-31, and 33-38 rejected under 35 U.S.C. 103(a) as being unpatentable over *Seale* as applied to claims 1 and 17 above, and further in view of *Beach et al* (US 6,042,556) and *Uchiyama et al* (US 4,958,639a).

Seale substantially discloses all claimed features in claims 2-16 and 18-38. However, Seale does not specifically disclose the features addressed below, which are supplemented by Beach et al and Uchiyama et al where the features include transducer's transmit methods and

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back end processor which are required to analyze the received reflected ultrasound energy described above.

Claims 2-6 and 19-22: In addition, Beach et al disclose of focal depth control based on time delay of the reflected signal received by the receiver to control the depth or distance of the focus. Also, Beach et al disclose of amplitude of peak signal of the delay to determine the depth of the ultrasound energy focus (col. 10, lines 42-61).

Claims 7-10, 23-27, and 34: Beach et al shows in step 84 in flow chart in figure 8 where the transducer elements 32 transmits burst of ultrasound energy from the transducer simultaneously. In steps 86-92, the receive delay of each transducer elements are adjusted from the simultaneous transmission from step 84 above. Beach et al also includes repeat loop immediately after step 92.

Claims 11-16 and 28-31: Beach et al's system and method includes data processing and control with microprocessor, i.e. computer, is used to implement the method of processing and controlling the ultrasound transducer (col. 6, lines 21-34). Beach et al shows that the received data is plotted in figures 10-12, which include obtaining and displaying reflected ultrasound energy and the data being single trace.

Claims 18 and 33: Beach et al anticipate all featured elements in claims 1, 17, 18, and 33. Beach et al discloses of an ultrasonic therapy system and method where an ultrasonic transducer 12 emits ultrasound energy beam 14 thru a path consisting of multiple tissue types. In addition, Beach et al disclose of a system controller 22 to control the timing of transmit and receive of the transmitter 26 and receiver 28, which control time delay, focus, and steering (col. 5, line 20 – col. 6, line 8). The time delay and phase control serves as distinguishing to the receive signal

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from the varying tissue characteristic (abstract; col. 4, lines 12-34). However, Beach et al do not specifically disclose the use of focal zone in HIFU or high-energy ultrasound burst and detect a disturbance in the transmission. Uchiyama et al teach that the high energy ultrasound therapy may be applied to treat patient with shock wave acoustic which causes disturbances or fluctuation in target area, which is detectable, by ultrasound (col. 2, lines 25-42; col. 3, line 11- col. 4, line 29).

Claims 35-38: Beach et al disclose in figure 8 that the ultrasound treatment is applied to volume of tissue where the control of the focus is achieved by the phase and time delay. More specifically, Beach et al converts the target volume measured from propagation time or time delay from the HIFU transducer element 32 to find range of tissue treatment region, therefore, Beach et al utilizes the delay and range (col. 9, lines 54-60).

Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Beach et al and Uchiyama et al's to fully disclose the transmission method and back end processor to improve Seale's method and apparatus.

6. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Seale, Beach et al*, and *Uchiyama et al* as applied to claims 17, 18, 20, and 29 above, and further in view of *Aida et al* (US 5,485,839).

Seale, Beach et al and Uchiyama et al substantially disclose of all claimed invention in claim 32. However, Seale, Beach et al or Uchiyama et al do not disclose of 3D imaging of ultrasound signal disturbance, i.e. tissue characterization from the ultrasound signal. Aida et al teach that a alternate imaging device such as MRI or CT can be used to obtain 3D image data

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and reconstruction of the images for display 17 to assess ultrasound therapy procedure which includes transmission of ultrasound energy into patient (col. 5, lines 37-63). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Aida et al to monitor the therapy of Seale, Beach et al or Uchiyama et al with MRI or CT, because Aida et al clearly teach that the ultrasound therapy such Beach et al and Seale can be monitor with secondary imaging system such as MRI and CT with 3D imaging capability.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

WLS

February 24, 2006


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